

Ca Calcium Sulfate

1 Nonproprietary Names

BP: Calcium Sulphate Dihydrate

PhEur: Calcium Sulfate Dihydrate

USP-NF: Calcium Sulfate

2 Synonyms

Calcium sulfate anhydrous anhydrite; anhydrous gypsum; anhydrous sulfate of lime; *Destab*; *Drierite*; E516; karstenite; muriacite; *Snow White*.

Calcium sulfate dihydrate alabaster; *calcii sulfas dihydricus*; *Cal-Tab*; *Compactrol*; *Destab*; E516; gypsum; light spar; mineral white; native calcium sulfate; precipitated calcium sulfate; satinite; satin spar; selenite; terra alba; *USG Terra Alba*.

3 Chemical Name and CAS Registry Number

Calcium sulfate [7778-18-9]

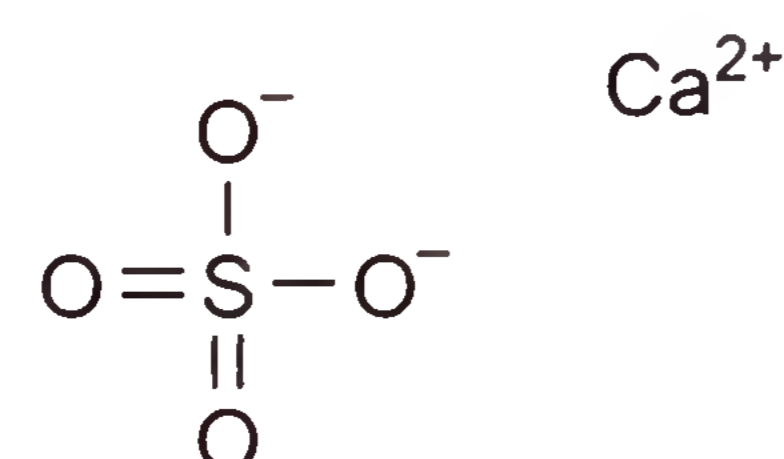
Calcium sulfate dihydrate [10101-41-4]

4 Empirical Formula and Molecular Weight

CaSO₄ 136.14

CaSO₄·2H₂O 172.17

5 Structural Formula



6 Functional Category

Desiccant; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Calcium sulfate dihydrate is used in the formulation of tablets and capsules. In granular form it has good compaction properties and moderate disintegration properties.^(1,2)

Anhydrous calcium sulfate is hygroscopic and is used as a desiccant. The uptake of water can cause the tablets to become very hard and to fail to disintegrate on storage. Therefore, anhydrous calcium sulfate is not recommended for the formulation of tablets, capsules, or powders for oral administration.

8 Description

Both calcium sulfate and calcium sulfate dihydrate are white or off-white, fine, odorless, and tasteless powder or granules.

9 Pharmacopeial Specifications

See Table I. See also Section 18.

10 Typical Properties

Acidity/alkalinity

pH = 7.3 (10% slurry) for dihydrate;

pH = 10.4 (10% slurry) for anhydrous material.

Angle of repose 37.6° for *Compactrol*.⁽²⁾

Compressibility see Figure 1.

Table I: Pharmacopeial specifications for calcium sulfate.

Test	PhEur 9.2	USP 40-NF 35 S1
Identification	+	+
Characters	+	—
Acidity or alkalinity	+	—
Arsenic	≤10 ppm	—
Chlorides	≤300 ppm	—
Heavy metals	—	≤10 ppm
Iron	≤100 ppm	≤100 ppm
Loss on drying		
Anhydrous	—	≤1.5%
Dihydrate	—	19.0–23.0%
Loss on ignition	18.0–22.0%	—
Assay	98.0–102.0%	98.0–101.0%

Density (bulk)

0.94 g/cm³ for *Compactrol*.⁽²⁾

0.67 g/cm³ for dihydrate;

0.70 g/cm³ for anhydrous material.

Density (tapped)

1.10 g/cm³ for *Compactrol*.⁽²⁾

1.12 g/cm³ for dihydrate;

1.28 g/cm³ for anhydrous material.

Density (true) 2.308 g/cm³

Flowability

48.4% (Carr compressibility index);

5.2 g/s for *Compactrol*.⁽²⁾

Melting point 1450°C for anhydrous material.

Particle size distribution 93% less than 45 μm in size for the dihydrate (*USG Terra Alba*); 97% less than 45 μm in size for the anhydrous material (*Snow White*). Average particle size is 17 μm for the dihydrate and 8 μm for the anhydrous material. For

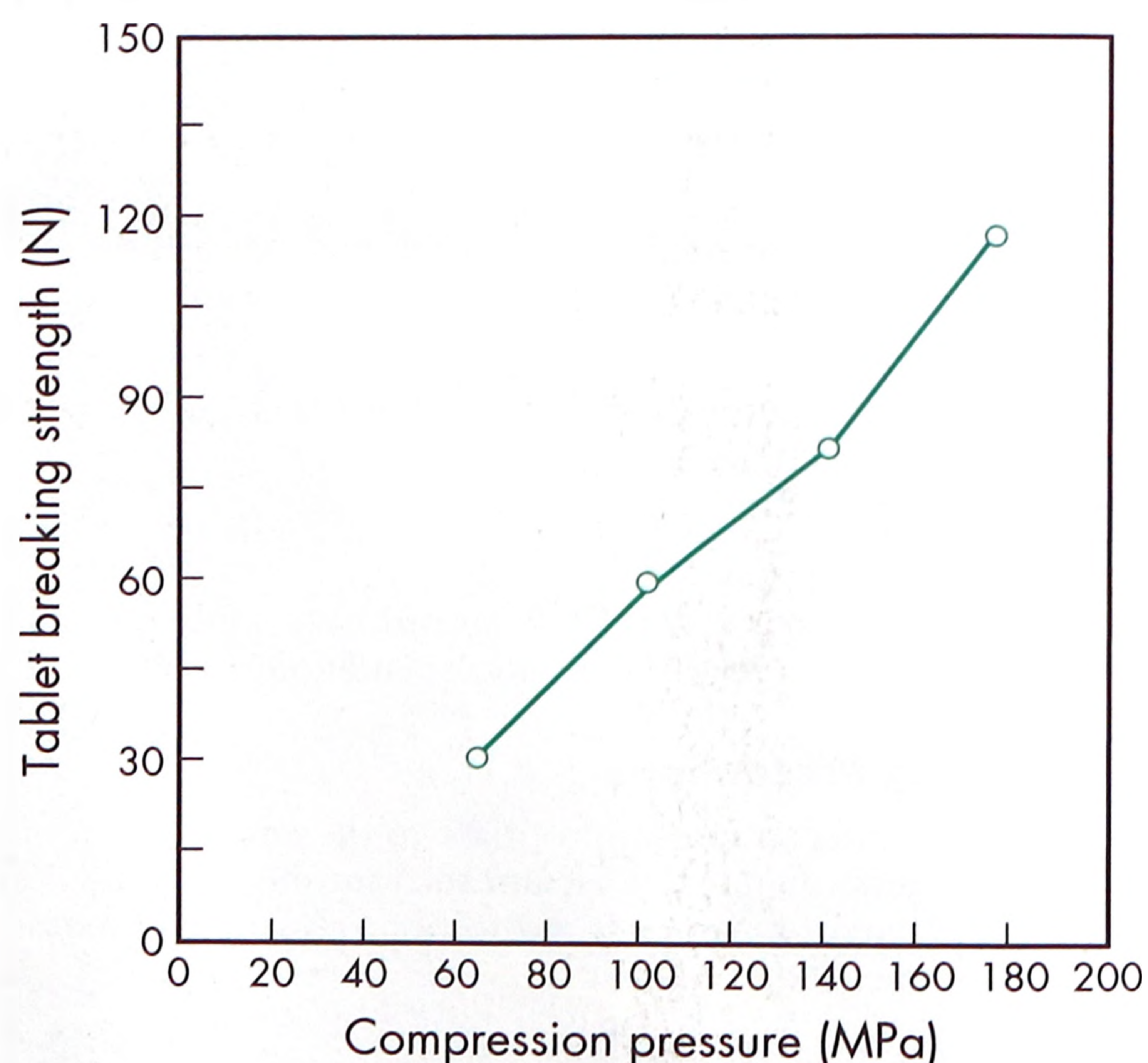


Figure 1: Compression characteristics of calcium sulfate dihydrate. Tablet weight: 700 mg.